UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,474	09/25/2003	Douglas McNeel	011335.52703US	4831

23911 7590 10/19/2004

CROWELL & MORING LLP
INTELLECTUAL PROPERTY GROUP
P.O. BOX 14300
WASHINGTON, DC 20044-4300

EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,474	MCNEEL, DOUGLAS	
	Examiner	Art Unit	
	Louis D Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 23-25, 28-30 and 32 drawn to a method for inducing an immune reaction to a prostatic acid phosphatase (PAP) in a mammal, comprising administering a recombinant DNA construct comprising a polynucleotide encoding PAP, and a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP, classified in class 514, subclass 44.

II. Claims 10-22, drawn to drawn to a method for inducing an immune reaction to a prostatic acid phosphatase in a mammal, comprising administering a first and second recombinant DNA constructs comprising polynucleotides encoding PAPs from two different species, classified in class 514, subclass 44.

III. Claims 26 and 27, drawn to a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP, and at least one copy of an immunostimulatory fragment comprising 5'-GTCGTT-3', classified in class 514, subclass 44.

IV. Claim 31, drawn to a pharmaceutical composition comprising a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP, and a suitable amount of GM-CSF classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, and II are patentably distinct inventions for the following reasons. In the instant case the different invention of group I is to a method for inducing an immune reaction to a prostatic acid phosphatase (PAP) in a mammal, comprising administering a recombinant DNA construct comprising a polynucleotide encoding PAP, while the invention of group II is to a method for inducing an immune reaction to a prostatic acid phosphatase in a mammal, comprising administering a first and second recombinant DNA constructs comprising polynucleotides encoding PAPs from two different species. The invention of group I includes a single DNA construct encoding PAP while the invention of group II requires an additional DNA construct encoding PAP from a different species than the first construct. The presence of an additional PAP construct from a different species makes the components and methodology of group II distinct in from the invention of group I.

Inventions I, III and IV, are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the different invention of group I is to a method for inducing an immune reaction to a prostatic acid phosphatase (PAP) in a mammal, comprising administering a recombinant DNA construct comprising a polynucleotide encoding PAP, and to a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP, while the inventions of groups III is to a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP and at least one immunostimulatory fragment and the invention of group IV is to a pharmaceutical composition comprising a DNA vaccine comprising

a plasmid vector comprising a polynucleotide sequence encoding PAP, and a suitable amount of GM-CSF. The method of group I can be performed using the vaccine alone without the further addition of the immunostimulatory fragment of group III or the GM-CSF of group IV. Further, the immunostimulatory fragment of group III or the GM-CSF of group IV make them materially different from the vaccine of group I since the immune response they induce will be substantially different than the vaccine alone.

Inventions II, III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the different method for inducing an immune reaction to a prostatic acid phosphatase in a mammal, comprising administering a first and second recombinant DNA constructs comprising polynucleotides encoding PAPs from two different species, while the inventions of groups III is to a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP and at least one immunostimulatory fragment and the invention of group IV is to a pharmaceutical composition comprising a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP, and a suitable amount of GM-CSF. The method of group II could be performed using adenoviruses or naked DNA constructs encoding PAPs rather than the vector of group III. Further, the method of group II can be performed using the vaccine alone without the further addition of the immunostimulatory fragment of group III or the GM-CSF of group IV. The immunostimulatory fragment of group III or the GM-CSF of group IV make them materially different from the

vaccine of group II since the immune response they induce will be substantially different than the vaccine alone. Finally, the presence of an additional PAP construct from a different species makes the components and methodology of group II distinct in from the inventions of group III and IV..

Inventions III, and IV are patentably distinct inventions for the following reasons. In the instant case the different invention of group III is to a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP, and at least one copy of an immunostimulatory fragment comprising 5'-GTCGTT-3', while the invention of group IV is to a pharmaceutical composition comprising a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP, and a suitable amount of GM-CSF. The vector of group III is materially different from the vector of group IV since it further comprises at least one copy of the fragment GTCGTT. The composition of group IV differs from group III since it has the additional component of a suitable amount of GM-CSF. The two inventions could be performed separately without the other.

Furthermore, searching the inventions of groups I-IV together would impose a serious search burden. In the instant case, the search of a method for inducing an immune reaction to a prostatic acid phosphatase (PAP) in a mammal, comprising administering a recombinant DNA construct comprising a polynucleotide encoding PAP, and a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP, a method for inducing an immune reaction to a prostatic acid phosphatase in a mammal, comprising administering a first and second recombinant DNA constructs comprising polynucleotides encoding PAPs from two different species, a DNA vaccine comprising a plasmid vector comprising a polynucleotide

sequence encoding PAP, and at least one copy of an immunostimulatory fragment comprising 5'-GTCGTT-3', and a pharmaceutical composition comprising a DNA vaccine comprising a plasmid vector comprising a polynucleotide sequence encoding PAP, and a suitable amount of GM-CSF are not coextensive. As such, it would be burdensome to search the inventions of groups I-IV together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy J Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER